

REMARKS**Status of the Claims**

Claims 1-43 have been canceled and new claims 44-85 added. Claims 44-83 correspond to canceled claims 1-7, 9-20, 22-34 and 36-43. Claims 44-85 are under examination.

Claim Objections

The claims were objected to for having a missing claim 35 and for claims 8 and 21 being of improper dependent form. Claims 8, 21 and 35 have been canceled herein and new claims 44-85 are properly numbered and in proper dependent form where appropriate.

35 U.S.C. § 112, first paragraph

Claims 27-34 and 36-43 stand rejected as being unenabled for us of the term “prophylactically.” Claims 27-34 and 36-43 have been replaced by new claims 68-75 and 76-83. New claims 68 and 76 do not use the term “prophylactically” rendering this rejection moot.

35 U.S.C. § 112, second paragraph

Claims 14-26 and 36-43 stand rejected as being indefinite for reciting amino acids other than L-arginine that “are not therapeutically effective.” Claims 14-26 and 36-43 have been replaced by new claims 56-67 and 76-83. New independent claim 56 does not recite “amino acids other than L-arginine that are not therapeutically effective” rendering this rejection moot.

35 U.S.C. § 103(a)

Claims 1-28, 30, 36-37 and 39 stand rejected as being unpatentable over Rothbard et al. (U.S. 2002/0009491). Applicants respectfully traverse this ground of rejection.

Claims 1-28, 30, 36-37 and 39 have been canceled herein and replaced by new claims 44-69, 71, 76-77 and 79. These claims are directed to compositions and methods for the “enhancement of keratinous tissues.” The compositions consist essentially of a polymer having

from 7 to 15 subunits and each subunit consists of an L-arginine or physiologically acceptable salt of L-arginine. Further the L-arginine subunits “enhance vasodilation through production of nitric oxide.” In contrast Rothbard discloses L-arginine polymers which are complexed with another therapeutic agent for the purpose of enhancing the penetration of the therapeutic agent through a biological barrier such as skin.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicants assert that Rothbard does not teach or suggest all the limitations of the claims for at least two reasons.

First, Rothbard does not teach or suggest that the L-arginine polymers “enhance vasodilation through production of nitric oxide” as recited in independent claims 44 and 56 of the present invention. In fact Rothbard is completely silent on the subject of nitric oxide. Second, Rothbard teaches that the L-arginine polymers are in the form of a non-covalent complex with the therapeutic agent (see Figures 1 and 2 and paragraph 44 of Rothbard). The use of consisting language in independent claims 44 and 56 excludes the presence of any additional components in the L-arginine polymers. Therefore, not only does Rothbard not teach or suggest nitric oxide but the structure of the L-arginine polymers of Rothabard are excluded by independent claims 44 and 56.

The examiner also combined Rothbard with Kull et al., Porter et al., Kent et al, Ribier et al. and Clark et al. in rejecting claims 29, 31-34, 38 and 40-43. These claims have been

replaced herein by new claims 70, 72-75, 78 and 80-83. These claims are directed to methods for promoting angiogenesis, enhancing the appearance of lips, enhance sensitivity of skin, stabilization or remodeling of fat, and the treatment of gum regression. As stated by the examiner, Rothbard does not teach or suggest the treatment of any of these conditions. The examiner relies on the combination of Rothbard with Kull, Porter, Kent, Ribier or Clark in an attempt to establish a *prima facie* case of obviousness. However, none of these references remedy the deficiencies in Rothbard discussed above. That is, Rothbard in combination with Kull, Porter, Kent, Ribier or Clark does not teach or suggest that the L-arginine polymers "enhance vasodilation through production of nitric oxide" and all the references rely on the formation of a non-covalent complex between the therapeutic agent and the L-arginine polymer that is excluded by the consisting of language of independent claims 44 and 56. Because the examiner has failed to establish a *prima facie* case of obviousness applicants respectfully request that these rejections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. **4649-4007US1**. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. **4649-4007US1**. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

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By:


Kenneth H. Sonnenfeld / Peter G. Foiles
Registration No. 33,285 / 46,477

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101
(212) 415-8700 Telephone
(212) 415-8701 Facsimile